ZyCARE Inc. • 3804 Sweeten Creek Rd. • Chapel Hill, NC 27514 • Phone: (919)419-7228 • Fax: (919) 419-9088

AUG 16 2005

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K050821.

807.92 (a)(1): Name: Zycare, Inc.

Address: 3804 Sweeten Creek Road
Chapel Hill, NC 27514

Phone: (919) 419-7228

Contact: Mr. Steve D. Holdaway, MBA

807.92 (a)(2): Device Name – trade name and common name, and classification

Trade name: CoagCare® Anticoagulation Management System (CoagCare®)

Common name: Software accessory to prescription-home use prothrombin time (INR) devices for effective anticoagulation management with warfarin

Classification: CoagCare® is considered an unclassified accessory to INR test systems; INR test systems are regulated under 21 CFR 864.7750, Class II: 81 GJS.

The device regulation for a "calculator/data processing module for clinical use" (21 CFR 862.2100) exempts such Class I devices from 510(k) requirements. This regulation is not entirely applicable, however, since the exemption only applies to data processors for clinical laboratory use, and not home use or use in clinic settings.

807.92 (a)(3): Identification of the legally marketed predicate device

The CoagCare® Anticoagulation Management System is substantially equivalent to the Diacare® Monitoring System, K882001, cleared October 18, 1988; the Diacare system was cleared for the clinical management of diabetes mellitus.

807.92 (a)(4): Device Description

The CoagCare system is a software accessory to prescription-home use prothrombin time (INR) devices for effective anticoagulation management with warfarin. *System Overview:* The system consists of two components, the CoagCare *Patient Interface* and the CoagCare *Caregiver Interface*, both of which are accessed through an internet browser. The interface provides a structured therapeutic regimen developed for the individual patient. It prompts the patient for INR values, symptoms, and other disease related data, and provides the patient with recommended doses of warfarin and an INR testing schedule that can be adjusted based on parameters specified by the patient's caregiver. The patient is given recommendations for warfarin doses for each day until the next time of required INR testing. In cases of marked abnormal INR readings or disease signs or symptoms suggestive of over-treatment, the *Patient Interface* instructs the patient to contact his/her healthcare provider for further instructions.

The second component of the CoagCare system is the *Caregiver Interface.* The caregiver monitoring the patient's anticoagulant therapy accesses the *Caregiver Interface* at least daily. The *Caregiver Interface* is programmed to automatically identify patient problems such as patients who report thromboembolic or hemorrhagic symptoms, failure to check their INR on a prescribed day, etc. The *Caregiver Interface* prioritizes problems requiring the caregiver's attention. Once patients have checked their INRs and transmitted their results, if the caregiver agrees with the warfarin dosing instructions provided by the *patient interface*, no further interventions are required for that day. Patients with markedly abnormal results or recurrent problems are prioritized for caregiver intervention, whereas stable patients are listed with their results, eliminating the need for direct patient contact by the caregiver. The *Caregiver Interface* also allows the caregiver to override therapeutic instructions provided by the *Patient Interface*, or send a text message to the patient through the *Patient interface.* (For more emergent issues, the patient can be contacted directly by the caregiver by telephone.)

807.92 (a)(5): Intended use

The CoagCare Anticoagulation Management System (CoagCare) is an interactive internet-based (web-based) software system for the long-term management of patients undergoing warfarin anticoagulation therapy. The system is an accessory to prescription home-use prothrombin time devices that measure International Normalized Ratios (INRs), and it facilitates remote clinical management between patient and caregiver.

807.92 (a)(6): Technological Similarities and Differences to Predicate

The following chart describes similarities and differences between the CoagCare system and the Diacare system (the predicate).

CHARACTERISTIC	CoagCare	Diacare (K882001)
Intended Use	Software (web-based) system used in the patient's home for the management and monitoring of INR levels and dosing recommendations in patients being treated with anticoagulation therapy (warfarin); automates supervision of patients	Hardware/software system used in the patient's home for the management and monitoring of glucose and insulin levels in patients being treated for diabetes; automates supervision of patients
System Functions	Screens the data for problems, prioritizes patient records for physician review, monitors implementation of a home medication dosing algorithm; physician can manage patients remotely	Screens the data for problems, prioritizes patient records for physician review, monitors implementation of a home medication dosing algorithm; physician can manage patients remotely
Route of Information Transfer	Secure internet web-site with dedicated servers	Direct server dial-in

CHARACTERISTIC	CoagCare	Diacare (K882001)
Data Output	Printable reports	Printable reports
Patient Identification	Secured through passwords and secure website	Hardware based, meter connected to phone line by patient
Safety Features	Requires tight professional oversight in the event of unexpected results or symptoms	Requires tight professional oversight in the event of unexpected results or symptoms
Testing Environment	Home use with professional oversight	Home use with professional oversight
System Components	Proprietary internet-enabled software, patient interface and care giver interface	Proprietary software, patient interface and care giver interface
Risk to Patient	Minimal, system will enforce contact with health care professional in the event of unexpected results/symptoms	Minimal, system will enforce contact with health care professional in the event of unexpected results/symptoms
Required IVD Component	Requires INR meter to obtain clinical INR results	Requires glucose meter to obtain clinical glucose results
Management Decision	Systems utilizes published and generally accepted algorithms to adjust medication doses and make treatment decisions	Systems utilizes published and generally accepted algorithms to adjust medication doses and make treatment decisions

The differences between the two data management systems do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Non-clinical data

Non-clinical studies are not relevant to software accessories.

807.92 (b)(2): Brief Description of Clinical Data

The CoagCare Anticoagulation Management System was evaluated in comprehensive clinical studies at three sites. Fifty-eight patients at Duke University Medical Center and 22 patients at the University of New Mexico Medical Center, and 20 patients from a private practice in Miami who had been on warfarin for at least six months were recruited for the study. Patients at the Duke and New Mexico sites were switched to home INR monitoring and followed with the CoagCare system for six months. Patients in the Miami site remained on the system from 3 to 4 months. The overall INRs of all patients averaged 62.5% time in therapeutic range (TTR) prior to the start of CoagCare. This value increased to 73.5% TTR during the study, an 11% and statistically significant improvement ($p=.008$). The site effect was non-significant ($p=.87$), suggesting that the improvement in TTR was not statistically distinguishable across the sites. The increase in TTR seen with the CoagCare system could reasonably interpreted to reflect a clinically important improvement. Caregivers at all 3 sites reported that it took between 15 and 25 minutes a day to manage between 20 and 58 patients. Due to the automation provided by CoagCare, managing 48 patients with CoagCare did not take much more time than managing 20. Between 92% and 100% of all patients reported that they preferred home management with CoagCare to traditional point-of-care treatment, that they felt that they were being monitored more closely with CoagCare and that their INRs were in better control with home management.

807.92 (b)(3): Conclusions from Clinical Testing

In summary, we have demonstrated that patients and caregivers can successfully use the CoagCare system to produce improved outcomes and a high degree of patient satisfaction. The studies show that the CoagCare system is safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2005

Mr. Steven D. Holdaway, MBA
Chief Executive Officer
ZyCare, Inc.
3804 Sweeten Creek Road
Chapel Hill, NC 27514

Re: k050821
Trade/Device Name: CoagCare Anticoagulation Management System (CoagCare®)
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation instrument
Regulatory Class: Class II
Product Code: KQG
Dated: July 25, 2005
Received: July 26, 2005

Dear Mr. Holdaway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if Known): K050821

Device Name: CoagCare Anticoagulation Management System (CoagCare®)

Indications for Use:

The CoagCare Anticoagulation Management System (CoagCare®) is an interactive, internet-based (web-based), rules-based expert software system for the long-term management of patients undergoing warfarin anticoagulation therapy. The system is an accessory to prescription home-use prothrombin time devices that measure International Normalized Ratios (INRs), and it facilitates remote clinical management between patient and caregiver. A caregiver may be a physician, nurse, pharmacist or licensed professional.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050821